

## **DETAILED ACTION**

### ***Priority***

This application claims benefit as a Continuation of U.S. Application No. 09/816,391 filed 26 March 2001 (abandoned). The instant application also claims benefit from foreign application JAPAN 2000-287688 filed 12 September 2000. Therefore, the application has been granted the benefit date, 12 September 2000 from the foreign application, JAPAN 2000-287688.

### ***OBVIOUS DOUBLE PATENTING***

The applicant's representative called the examiner (see attached Interview Summary), to discuss the ODP rejection. It was concluded that according to MPEP 804 I.B.1., "If a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." In the ODP rejection against claims from copending application, 11/718680, the instant application is the earlier-filed application. Therefore, the examiner withdraws the ODP rejection.

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The prosecution history provides evidence for allowability.

Obviousness Double Patenting rejection of senior application was withdrawn.

While the *B. longum* HU promoter was known to be highly expressive, it had not been isolated to the degree defined in the instant claims and plasmid. Prior to the claimed invention, large nucleic acids fragments comprising the *B. longum* HU promoter and terminator were submitted into the public record as part of the sequencing of the genome of *B. longum*. At the time the genomic sequencing was performed, the functions of these sequences were unknown. Therefore, in addition to the reasons provided by the applicant in the prosecution history, a skilled artisan would not have been guided by scientific reasoning or the available knowledge in the art to use the *Bifidobacterium longum* HU promoter to express an antitumor substance in a *Bifidobacterium longum* vector.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Conclusion**

Claims 47-51, 53-64, and 73-79 are allowed.

#### **Examiner Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/  
Patent Examiner, Art Unit 1633